STATE OF MICHIGAN

DEPARTMENT OF LABOR & ECONOMIC GROWTH

OFFICE OF FINANCIAL AND INSURANCE SERVICES

Before the Commissioner of Financial and Insurance Services

In the matter of

The Estate of XXXXX
Petitioner **File No. 87329-001**

v

Health Alliance Plan of Michigan
Respondent
_____/

Issued and entered
This 24th day of March 2008
by Ken Ross
Commissioner

ORDER

I
PROCEDURAL BACKGROUND

On January 23, 2008, XXXXX, special personal representative of the estate of XXXXX (Petitioner),[1] filed a request for external review with the Commissioner of the Office of Financial and Insurance Services under the Patient's Right to Independent Review Act, MCL 550.1901 *et seq*. On January 28, 2008, after a preliminary review of the material submitted, the Commissioner accepted the request for external review.

Initially this case appeared to involve only contractual issues so the Commissioner did not assign it to an independent review organization for an analysis of the medical issues. However, upon further evaluation the Commissioner determined this case would benefit from a review by an IRO. On February 20, 2007, the IRO completed its review and sent it to the Commissioner.

[1] The Petitioner died on November 7, 2007, so the term "Petitioner" when used in this order include the estate's special personal representative.

II
FACTUAL BACKGROUND

The Petitioner had primary health care coverage as a member of Health Alliance Plan (HAP), a health maintenance organization. Medicare Part A provided his secondary health care coverage.

In the spring of 2006 the Petitioner was diagnosed with prostate cancer and in the summer of that year he received CyberKnife radiotherapy from Dr. XXXXX at the XXXXX (the Center) in XXXXX, XXXXX. Dr. XXXXX and the Center are outside HAP's service area and are not affiliated providers with HAP, i.e., they have not signed contracts to provide services to HAP members.

The Petitioner requested coverage for the services. HAP denied the request[2] and the Petitioner appealed. After the Petitioner exhausted HAP's internal grievance process, HAP maintained its denial and sent the Petitioner its final adverse determination letter dated November 21, 2007.

III
ISSUE

Did HAP properly deny the Petitioner's request for coverage of services from a non-affiliated provider under the terms of his coverage contract?

IV
ANALYSIS

PETITIONER'S ARGUMENT

From August 7 through August 11, 2006, the Petitioner had CyberKnife treatment from Dr. XXXXX at the Center. The charge was $89,680.20.

The Petitioner says that the reason he decided to have the CyberKnife therapy with Dr. XXXXX instead of external beam radiation therapy (EBRT) at Henry Ford was because with

[2] HAP issued a denial of services dated September 19, 2006, but does not explain any of the events that took place during June 2006 when the Petitioner made several phone calls to HAP to request care from a non-affiliated provider.

CyberKnife therapy there would be less peripheral tissue damage and fewer long and short term side effects. In addition, the CyberKnife therapy was less invasive and less risky and could be done on an outpatient basis. Further, the Petitioner could resume normal activities immediately following treatment and avoid the fatigue and pain associated with EBRT. There was also less chance of joint immobility and improved urinary symptoms.

The Petitioner says his primary care physician, Dr. XXXXX, advised him that the time it would take to pursue a referral was unacceptable in view of his diagnosis. The Petitioner says his oncologist also decided against providing a referral upon the advice of his superiors.

The Petitioner argues that given the circumstances (the urgent need for treatment, the advice of his physicians that he did not have time to pursue authorization, and HAP's failure to respond timely in providing a referral) it was necessary to have the treatment from a non-affiliated provider.

The Petitioner believes HAP should cover the CyberKnife therapy by the non-affiliated provider.

HAP'S ARGUMENT

In the final adverse determination letter dated November 21, 2007, HAP's grievance committee denied coverage for the surgery, explaining:

> HAP Members must utilize their selected medical centers, physicians and hospitals to obtain covered services. By means of definition, covered services are those medically necessary health care services, which have been authorized and provided in accordance with HAP's accepted referral and practice policies.
>
> Currently and at the time of [the Petitioner's] diagnosis, CyberKnife Radiotherapy is not the standard of care for treating prostate cancer. Recent clinical literature indicates that there is a lack of evidence in peer-reviewed scientific literature demonstrating the safety and efficacy of stereotactic radiosurgery in comparison to other radiotherapy treatments or other nonradiotherapy treatment for this specific diagnosis. Therefore, because CyberKnife Treatment has not been proven to provide any medical advantage over traditional therapies, such as External Beam Radiation Therapy (EBRT), for the treatment of prostate cancer and because [the Petitioner] obtained this treatment out of plan and without prior authorization from HAP, your request…for primary payment of claims totaling $89,680.20 incurred at the XXXXX Center in XXXXX, must remain denied.

HAP says that the Petitioner received CyberKnife surgery without prior authorization and that care from a non-affiliated provider without prior approval is specifically excluded under the contract. HAP believes it denial was appropriate.

COMMISSIONER'S REVIEW

HAP's contract explicitly excludes coverage for services that are experimental or investigational (nonstandard) or are rendered by a non-affiliated provider without prior approval from HAP. The contract says in pertinent part:

> **SECTION 5 – EXCLUSIONS AND LIMITATIONS**
> **The following are not covered under this Contract:**
> *** * ***
> **5.1 Non-Covered Services**
> *** * ***
> (e) **Experimental and Investigational Services**
> Any drug, treatment, device, procedure, service or benefit that is experimental or investigational.
>
> (1) A drug, treatment, device, procedure, service or benefit may be considered experimental or investigational by HAP is it meets one of the following criteria:
> * * *
> F. The predominant opinion among experts as expressed in the published authoritative literature is that further research is necessary in order to define safety, toxicity, efficacy or efficacy in comparison to conventional alternatives.
> *** * ***
> **5.2 Other Exclusions**
>
> (a) Services provided by a non-Affiliated Provider, except for an Emergency or Urgent Care or when specifically approved in advance by HAP or its designee. [Emphasis added]

The contract also places certain responsibilities on the Petitioner:

> **6.2 Responsibilities**
> *** * ***
> (j) You have a responsibility at the time of enrollment to select a single Physician Network or medical group and a single PCP [personal care physician] for your medical care. For selected Physician Networks or Medical Group, most Covered Services require a referral from your PCP, and most referrals from your

> PCP will be to Affiliated providers within your chosen Physician Network or Medical Group.
>
> (k) You have a responsibility to satisfy all referral, authorization and assigned network requirements described in this Contract, regardless of whether HAP pays as the primary insurer or otherwise.

The contract also says (page 1):

> Because Health Alliance Plan is an HMO, the services covered under this Contract must be provided, arranged or authorized in advance by your personal care physician (PCP). Your PCP is an Affiliated Provider that you choose who is primarily responsible for providing or arranging for health care services for you. In some cases, your PCP will also need to have services approved by us.

HAP's primary reason for not approving the CyberKnife radiotherapy was that it determined it was nonstandard care for treating prostate cancer, i.e., the efficacy of the service had not been established.

To help the Commissioner resolve the issue of whether HAP's denial of coverage for the CyberKnife was correct, the matter was assigned to an independent review organization (IRO) for the recommendation of an expert. The IRO physician reviewer is certified by the American Board of Radiology with a subspecialty certification in radiation oncology and is published in peer reviewed medical literature. The reviewer recommended upholding HAP's denial of coverage. The IRO report includes the following conclusion:

> The clinical data from well-conducted randomized controlled or cohort trials is lacking in the prevailing peer-reviewed published medical literature to conclude that the use of the CyberKnife Robotic Radiosurgery System, for delivery of image-guided robotic linear accelerator-based stereotactic radiosurgery, has been proven to be safe and effective for the treatment of localized prostate carcinoma.
>
> * * *
>
> [A]t the present time, clinical outcome data on the safety and efficacy of image-guided stereotactic radiosurgery, such as CyberKnife, for localized prostate cancer has not been published in peer reviewed journals. Without such data, CyberKnife for prostate cancer is to be considered investigational at the present time, as well as in 2006.

The IRO reviewer's recommendation, based on extensive expertise and professional judgment, is afforded deference by the Commissioner. The Commissioner can discern no

reason why the IRO reviewer's judgment should be rejected in the present case. Therefore, the Commissioner accepts the IRO reviewer's conclusion that CyberKnife radiotherapy is investigational and not the standard of care for prostate cancer, and finds that HAP's denial of coverage on that basis was correct.

HAP also denied coverage because the services were not approved in advance. The Petitioner's health care contract clearly requires advance approval for care from non-affiliated providers -- except for emergencies and urgent care, and the Petitioner has not claimed that either exception applies.

The Petitioner said that he felt he did not have time to get a referral first because it would have delayed treatment. However, he did make an attempt to get prior approval. It appears from information in the file that on June 27, 2006, the Petitioner was in contact with HAP nurses regarding a referral to a non-affiliated provider.[3] However, nothing in the record clearly indicates what action, if any, HAP took in response to the requested authorization. HAP possibly did not respond to the Petitioner in writing until September 2006 when a request for payment was reviewed as a retroactive request for authorization. Nevertheless, the Petitioner did not follow the requirements of the contract and obtain prior approval for services from a non-affiliated provider.

What is also missing from the record is any indication that HAP advised the Petitioner about his right (pursuant to Section 2213 of the Insurance Code, MCL 500.2213) to request an expedited internal grievance and an expedited external review of any denial of a referral. Given the fact that it was HAP's position that the treatment at the Center was nonstandard, it is highly unlikely that a referral to the Center and Dr. XXXXX would have been made. The record also shows that the Petitioner was told in advance about the availability of standard EBRT from an

[3] In fact, according to HAP's second level grievance summary note date July 2, 2007, the Petitioner made several calls between June 2 and June 30, 2006, about a referral.

affiliated provider and it may be that the Petitioner chose to go to the Center because he wanted the CyberKnife therapy in any case and knew it was not available from an affiliated provider. All the same, HAP should have been more diligent in informing the Petitioner about his grievance rights.

The Commissioner, finding that the CyberKnife therapy is experimental or investigational, upholds HAP's denial of coverage on the basis that such nonstandard treatment is excluded under the terms of the Petitioner's contract.

V
ORDER

The Commissioner upholds HAP's November 21, 2007, final adverse determination in this matter denying coverage for the Petitioner's nonstandard services from a non-affiliated provider. The denial was in accord with the terms and conditions of the Petitioner's subscriber contract.

This is a final decision of an administrative agency. Under MCL 550.1915, any person aggrieved by this Order may seek judicial review no later than sixty days from the date of this Order in the Circuit Court for the county where the covered person resides or in the Circuit Court of Ingham County. A copy of the petition for judicial review should be sent to the Commissioner of the Office of Financial and Insurance Services, Health Plans Division, Post Office Box 30220, Lansing, MI 48909-7720.